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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/316,515 | 05/21/1999 | DAVID B. KRIG | 279.112US1 | 7896 |

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EXAMINER

EVANISKO, GEORGE ROBERT

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3762

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DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/316,515

Applicant(s)

KRIG ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 55-57 and 90 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 8, 23-29, 33, 35, 50-54, 58, 59, 62-65, 67, 68, 71, 73, 88, 89, 91 is/are rejected.
- 7) ☒ Claim(s) 3-5, 7, 9-22, 30-32, 34, 36-49, 60, 61, 66, 69, 70, 72 and 74-87 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 35,36.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 10/16/03 has been entered.

Information Disclosure Statement

The information disclosure statement filed 10/16/03 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the fifth non-patent literature publication ("Vitatron Medical Harmony... Guide") does not contain a date of publication. It has been placed in the application file, but the information referred to therein for that particular reference has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

The examiner is requesting, under 37 CFR 1.105, information relating to the IDS publication "Pacemaker System Guide for PULSAR MAX II; Multiprogrammable Pacemakers". The examiner is requesting the complete document. In addition, the examiner is requesting that

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the attorney/agent and inventors submit any non-patent literature, published application, or patent (US or foreign) that relates to the claimed invention, specifically to ventricular rate regulation, that was published before the effective filing date of this application (May 21, 1999).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 6, 8, 26-29, 33, 35, 53, 54, are rejected under 35 U.S.C. 102(a) as being anticipated by “Pacemaker System Guide...Pacemakers”. Page 6-39 discusses the use of the VRR pacing mode and its use during the Atrial Tachy Response mode. For claims 6 and 33, the publication states that a weighted sum is used and/or the coefficients are both equal to 1. For claims 8 and 35, since the paced rate is different than the sensed rate, the weighted sum will use two different equations and/or have all coefficients equal to 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 58 and 59 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Pacemaker publication. It is inherent that the pacemaker contain some sort of controller for calculating the pacing rate and controlling the system.

In the alternative, the Pacemaker publication discloses the claimed invention except for the controller calculating the pacing rate and controlling the system. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacer system as taught by the Pacemaker publication, with a controller for calculating the pacing rate and controlling the system since it was known in the art that pacemakers use a controller to calculate the pacing rate and controller the system to provide an automated system that is easy to operate and that does not require constant input from the patient or physician.

Claims 63-65, 67, 68, 71, 73, 88, 89, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Pacemaker publication.

The Pacemaker publication discloses the claimed invention except for the controller, filter, and registers for calculating the pacing rates and storing the rates, providing pacing therapy based on a second sensor indicated interval, using an FIR or IIR filter for calculating the rates, the use of a leadwire to couple the ventricular sense and therapy circuits to the heart, and a remote programmer for communicating with the controller. It would have been obvious to one

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having ordinary skill in the art at the time the invention was made to modify the pacer as taught by the Pacemaker publication, with a controller, filter, and registers for calculating the pacing rates and storing the rates, providing pacing therapy based on a second sensor indicated interval, the use of a leadwire to couple the ventricular sense and therapy circuits to the heart, and a remote programmer for communicating with the controller since it was known in the art that pacemakers provide; a controller, filter, and registers for calculating the pacing rate and storing the rates to provide a conventional processing means to easily control the system, clean the data, and store the information for later use; pacing therapy based on a second sensor indicated interval to allow the pacing rate to more accurately match the physiological need of the patient; the use of a leadwire to couple the ventricular sense and therapy circuits to the heart to provide therapy directly to the heart and sense directly from the heart; and a remote programmer for communicating with the controller to allow the pacer controller to be externally programmed with different parameters and control algorithms.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the pacer as taught by the Pacemaker publication in view of one having ordinary skill in the art with the filters being FIR or IIR filters, because Applicant has not disclosed that the filters being FIR or IIR filters provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any filter as taught by the Pacemaker publication in view of one having ordinary skill in the art, because it would provide a means to easily calculate and clean the data for determining the pacing interval.

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Therefore, it would have been an obvious matter of design choice to modify the Pacemaker publication in view of one having ordinary skill in the art to obtain the invention as specified in the claim(s).

Claims 23-25, 50-52, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Pacemaker...Pacemakers".

The Pacemaker publication discloses the claimed invention except for providing pacing therapy based on a second sensor indicated interval, providing the shorter of the first and second interval as the pacing interval, and bounding the intervals to upper and lower limits. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacing system as taught by the Pacemaker publication, with a providing of pacing therapy based on a sensor indicated interval, providing the shorter of the first and second interval as the pacing interval, and bounding the intervals to upper and lower limits since it was known in the art that pacemakers provide: pacing therapy based on a sensor indicated interval to more accurately match the pacing rate/interval to the physiological need of the patient; providing the shorter of the first and second interval as the pacing interval to provide a greater pacing rate that is a better indicator of the patients pacing needs; and bounding the intervals to upper and lower limits so the pacemaker does not pace the patient too fast or too slow.

Allowable Subject Matter

Claims 55-57 and 90 are allowed.

Claims 3-5, 7, 9-22, 30-32, 34, 36-49, 60, 61, 66, 69, 70, 72, and 74-87 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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George R Evanisko
Primary Examiner
Art Unit 3762

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GRE
February 27, 2004